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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Scott E. Jahns

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,861	Applicant(s) JAHNS ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-29 and 48-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20-29 and 48-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-3-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 18 July 2008.

Response to Arguments

Applicant's arguments filed 18 July 2008 with respect to the 35 U.S.C. 103(a) rejection to Claim 1 under Diaz in view of Burbank have been fully considered but they are not persuasive. Applicant argues that Diaz in view of Burbank is not used for anastomosis. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant further argues that Diaz in view of Burbank does not teach a removable seal attached to a tether. This is not persuasive because Diaz clearly shows a seal (100) that is attached to a tether (210).

Applicant's arguments with respect to claims 21-27 and 28-29 and 48-57 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-4, 9-12, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Burbank, et al. (US Patent 6,689,071).

Claim 1: Diaz'674 discloses a wound closure device that contains a cutting mechanism (at the distal end 302 of element 300, see Figure 5); a seal (100) attached to a tether (210) and a tool body (300) fixed and stationary to the cutting mechanism. The tool body has a proximal opening and a distal opening (see Figure 5) and an inner lumen. The seal is movable distally and proximally with respect to the cutting mechanism (see Figures 6-9).

Diaz'674 does not disclose the use of an electrode on the cutter.

Burbank'071 teaches a cutting device (102) that contains an electrode (126) because using RF energy to cut tissue is more efficient than cutting with a blade because it does not need to be frequently replaced like blades (column 2, lines 26-55). Regarding Claims 5-7, Burbank'071 teaches a metallic conductor (128) (column 5, lines 6-18) that delivers RF energy (column 4, lines 50-55) to the electrode (128) (column 5, lines 34-40). It would have been obvious to one skilled in the art at the time the invention was made to modify the cutter taught by Diaz'674 with an RF cutter taught by

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Burbank'071 because RF cutters do not need to be replaced because they do not get dull.

Claims 2-4, 11, 12: Diaz'674 discloses a shaft/rod/tether (210) attached to the seal.

Claim 10 and 18: Diaz'674 teaches a plurality of ribs (111, 122).

Claim 9 and 20: Diaz'674 teaches that the seal can be flexible or absorbable (column 3, lines 15-22).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Burbank'071, as applied to Claim 1, in further view of Fortune et al. (US Patent Application 2004/0215231).

Diaz'674 in view of Burbank'071 teach the limitations of Claims 8, except for the use of a coating.

Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by Diaz'674 in view of Burbank'071 with a coating taught by Fortune'231 to improve bonding of the seal with the vessel wall and improve the quality of the seal.

Claims 13-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Burbank'071, as applied to Claim 1, in further view of LeMole'369.

Diaz'674 in view of Burbank'071 teach the limitations of Claims 13-14 except for an inflatable seal.

LeMole'369 teaches a seal (302) that contains inflatable chambers (column 7, lines 58 to column 8, line 35) in order to move the seal between a collapsed and expanded configuration. The claim would have been obvious because the substitution of the known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Burbank'071, as applied to Claim 1, in further view of Blatter (US Patent 6,248,117).

Diaz'674 in view of Burbank'071 teach the limitations of Claims 15-17 and 27-29, except for an opening.

Blatter'117 teaches an opening (that wire 150 passes through) in the sealing member (160) in order to pass a wire for piercing the wall of a blood vessel (column 21, lines 31-43). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal of Diaz'674 in view of Burbank'071 with a hole taught by Blatter'117 in order to pass a piercing wire.

Claim 21, 22, 24-26, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Mollenauer et al. (US Patent 6,918,331).

Claim 21, 28, 29: Diaz'674 discloses a wound closure device that contains a cutting mechanism (at the distal end 302 of element 300, see Figure 5); a seal (100) and a tool body (300) fixed and stationary to the cutting mechanism. The tool body has a proximal opening and a distal opening (see Figure 5) and an inner lumen. The seal is

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movable distally and proximally with respect to the cutting mechanism (see Figures 6-9).

Mollenauer'331 teaches a seal (Figure 12) that contains inflatable chambers (50) in order to move the seal between a collapsed and expanded configuration, and an opening (47) for the purpose of allowing devices to enter the body through the lumen (see Figure 17) . The claim would have been obvious because the substitution of the known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim 22: Mollenauer'331 teaches a lumen (51) that is coupled to the inflatable chamber.

Claim 24: The seal of Mollenauer'331 is flexible.

Claim 25: Diaz'674 teaches that the seal contains one or more ribs (112, 122).

Claim 26: Diaz'674 discloses a shaft/rod/tether (210) attached to the seal. Claims 23 and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319, as applied to Claim 21, in further view of Fortune'231.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Mollenauer'331, as applied to Claim 21, in further view of Fortune'231.

Diaz'674 and Mollenauer'331 teach the limitations of Claims 23, except for the use of a coating (Claim 23) and ribs in the sealing member (Claim 25).

Claim 23: Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by Diaz'674 and LeMole'369 with a coating taught by Fortune'231 to improve bonding of the seal with the vessel wall and improve the quality of the seal.

Claim 48, 50, 51, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz (US Patent 5,690,674) in view of Gianturco (US Patent 5,258,000).

Claim 48 and 51, 55, 56: Diaz'674 teaches a wound closure device that contains a cutting mechanism (at the distal end 302 of element 300, see Figure 5); a seal (100) with a plurality of sealing members/ribs (111, 122) that has a delivery configuration (Figure 6) and a deployed configuration (Figure 10) and a tool body (300) fixed and stationary to the cutting mechanism. The tool body has a proximal opening and a distal opening (see Figure 5) and an inner lumen. The seal is movable distally and proximally with respect to the cutting mechanism (see Figures 6-9).

Diaz'674 does not teach a seal that contains multiple seal members intended for placement within the puncture.

Gianturco discloses a device (Figure 6) for puncture closure that contains two closure members (13, 16) that are intended for placement within a puncture. It would have been obvious to one of ordinary skill in the art to use the closure device of Gianturco because it is a simple substitution of equivalent elements.

Claim 50: Diaz'674 teaches that the seal can be flexible (column 3, lines 15-22).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674 in view of Gianturco'000, as applied to Claim 48, in further view of Fortune'231.

Diaz'674 in view of Gianturco'000 teaches the limitations of Claim 49, except for the use of a coating.

Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by Diaz'674 with a coating taught by Fortune'231 to improve bonding of the seal with the vessel wall and improve the quality of the seal.

Claims 52, 53, 54 and 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz'674v in view of Gianturco'000, as applied to Claim 48, in further view of Blatter (US Patent 6,248,117).

Diaz'674 in view of Gianturco'000 teaches the limitations of Claims 57, except for an opening.

Blatter'117 teaches an opening (that wire 150 passes through) in the sealing member (160) in order to pass a wire for piercing the wall of a blood vessel (column 21, lines 31-43). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal of Diaz'674 with a hole taught by Blatter'117 in order to pass a piercing wire.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773